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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,386	05/15/2006	Jonathon Mark Tinsley	117-585	6582
23117	7590	08/31/2007		
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER STOICA, ELLY GERALD	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 08/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/579,386	Applicant(s) TINSLEY, JONATHON MARK	
	Examiner Elly-Gerald Stoica	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25,29,30 and 35-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-25,29,30 and 35-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :05/15/2006; 07/07/2006; 08/02/2006; 08/24/2006..

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I claims 1-17 and 43-46 drawn to a method of detection of a modulating agent and a kit for its detection.

Group II, claims 18-20 and 23, drawn to modulating agent.

Group III, claims 21-22, drawn to a method of modulating the activity of a peptide.

Group IV, claims 24 and 25, drawn to a method of treatment using specific antibodies or binding agent.

Group V, claims 29 and 30, drawn to a method of activating a signaling pathway.

Group VI, claims 35-38, 41, and 42, drawn to a method of diagnosis of a disease comprising PCR.

Group VII, claims 39 and 40, drawn to a method of diagnosis of a disease comprising two binding peptides.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: claim 18 is the first product claim since claim 1 is directed towards detection, which is a not a process of

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making but a process of using. As such, claim 18 encompasses antibodies against MIP-4, which were known in the prior art, as evidenced by Li et al. (WO 95/17092, 06/29/1995, cited by the Applicant).

The agent of Invention I is related to the method of Invention I, III, IV and V, as product as process of use. The agent of invention II can be used in any of the processes of Inventions I, III, IV and V.

The agent of Invention II is independent of the methods of Inventions VI and VII, since the product of Invention II is not required to perform the method of Inventions VI or VII.

Each of the Inventions I, III, IV, V are directed to related methods that are different from each other, since they have different functions, mode of operation and design.

Each of the inventions VI and VII are drawn to unrelated inventions from each other and from Inventions I, III, IV, and V.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If the Applicant elects Invention I, the categories of species are as follows:

- a. Category A: a polypeptide, an antibody or antigen-binding fragment thereof, a lipid, a carbohydrate, a nucleic acid or a chemical compound.
- b. Category B: label displacement, surface plasmon resonance, fluorescence resonance energy transfer, fluorescence quenching or fluorescence polarization.
- c. Category C: a radioisotope, a fluorophore, a quencher of fluorescence, an enzyme, an affinity tag or an epitope tag.
- d. Category D: measurement of guanosine nucleotide binding, GTPase activity, adenylate cyclase activity, cyclic adenosine monophosphate (cAMP), Protein Kinase C activity, phosphatidylinositol breakdown, diacylglycerol, inositol

triphosphate, intracellular calcium, MAP kinase activity or reporter gene expression.

e. Category E: synthetic liposomes; virus-induced budding membranes; artificial lipid bilayer; a membrane fraction from cells expressing the CCRL2 polypeptide.

If the Applicant elects Invention IV or VI, the species are as follows:

a. Category F: chronic obstructive pulmonary disease (COPD), bronchitis, emphysema, an inflammatory bone disorder, psoriasis, inflammatory bowel disease, an inflammatory brain disorder, atherosclerosis, endometriosis, autoimmune deficiency syndrome (AIDS), lupus erythematosus, allograft rejection, rheumatoid arthritis or allergic inflammation, obesity, obesity-related insulin resistance, autoimmune disease, contact hypersensitivity, cancer.

Applicant is required, in reply to this action, if Invention I is elected for prosecution, to elect a single species **from each of the categories A-E** to which the claims shall be restricted if no generic claim is finally held to be allowable. If any of the Inventions IV or VI is elected for prosecution, Applicant is required, in reply to this action, to elect a single species **category F** to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Category A, claim 4; Category B, claim 6; Category C, claim 8; Category D, claim 10; Category E, claim 17; Category F, claim 25 and partially claim 42.

Claim 24 is generic for category F.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they either have different structures and functional properties or represent different diseases with various etiologies, methods of diagnostic and treatment.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elly-Gerald Stoica whose telephone number is (571) 272-9941. The examiner can normally be reached on 8:30-17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



EILEEN B. O'HARA
PRIMARY EXAMINER